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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,297	08/24/2005	Jonas Angstrom	0933-0232PUS1	6676

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EXAMINER	
BLAND, LAYLA D	
ART UNIT	**PAPER NUMBER**
1623	

NOTIFICATION DATE	DELIVERY MODE
01/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/518,297	ANGSTROM ET AL.	
	Examiner	Art Unit	
	Layla Bland	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-104* is/are pending in the application.

4a) Of the above claim(s) *76-91 and 98-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *92-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/17/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group III, claims 92-97, and the species (LnNT and Neu5Acα3Galβ4Glc) in the reply filed on December 5, 2007 is acknowledged. The traversal is on the ground(s) that Prieto et al. is not relevant prior art because the therapeutic effects of the individual components in Prieto et al. have not been established in the article. This is not found persuasive because the technical feature linking groups I-VII is a combination of at least two compounds of formula (I) and Prieto et al. (U.S. 6,045,854, April 4, 2000) teach an infant formulation containing Lacto-N-Fucopentose II, Lacto-N-Fucopentose III, Lacto-N- neoTetraose, Lacto-N-fucopentaose V and Lacto-N-Tetraose [column 9, Example 3 and column 3, lines 25-45], all of which are encompassed by formula (I). Furthermore, Prieto et al. do disclose that oligosaccharides protect infants from viral and bacterial infections, promote growth of beneficial bacteria, etc. [column 1, lines 26-64]. Thus, the compositions taught by Prieto et al. are therapeutic compositions.

The requirement is still deemed proper and is therefore made FINAL.

This application is a national stage entry of International Application No. PCT/FI03/00528, filed June 30, 2003, and claims foreign priority to Finnish Applications No. 2002275, filed June 28, 2002 and 20030564, filed April 14, 2003. The certified copy of the priority has been filed with the instant Application.

Claims 76-104 are pending in this application. Claims 76-91 and 98-104 are withdrawn from consideration as being drawn to a non-elected invention. Claims 92-97 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 92-97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of gastrointestinal bacterial infections, does not reasonably provide enablement for the prevention of gastrointestinal bacterial infections or the treatment/prevention of all bacterial infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention.

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method of treatment for a bacterial infection, wherein a pharmaceutically or therapeutically or prophylactically effective amount of a composition is administered to a subject in need. Thus, the claims taken together with the specification imply that any bacterial infections can be treated or prevented (based on prophylactically effective amount) using the composition of claim 76.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Miller-Podraza et al. (WO 02/056893, July 25, 2002, PTO-1449 submitted December 17, 2004) teach the use of oligosaccharides for the treatment of conditions due to *Helicobacter pylori* [see abstract]. Vanmaele et al. (WO 00/51644, September 8, 2000, PTO-1449 submitted December 17, 2004) teach the use of oligosaccharides for the treatment of conditions mediated by *E. coli* [see abstract]. Prieto et al. (US 6,045,854, of record) teach that oligosaccharides protect infants from bacterial

infections of the respiratory, gastrointestinal, and urogenital tracts [column 1, lines 62-64].

Merck Manuals Online (Bacterial Infections – Introduction) teaches that there are many types of bacterial infections which require different treatments [entire document].

The term "bacterial infection" is very broad and encompasses such diseases as anthrax, tetanus, plague, typhoid fever, gas gangrene, smallpox, necrotizing fasciitis, and many others.

The term "infection," given its broadest reasonable interpretation, is interpreted as invasion of the body by pathogenic microorganisms. While the specification is enabling for treatment of conditions caused by infection and for inhibiting the growth of pathogenic microorganisms in the body, it is not enabling for the prevention of invasion by microorganisms.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for the treatment of *E. coli* and *Helicobacter* infections.

However, the specification does not provide guidance for the prevention of bacterial infections or the treatment of bacterial infections other than gastrointestinal infections. For example, no guidance is given as to the amounts and mode of administration of oligosaccharides of claim 76 which would be effective for the treatment of necrotizing fasciitis.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the breadth of the claims, the recitation of "prophylactically effective," the broadest reasonable interpretation of infection, and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 92-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 92 (and dependent claims) is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the recitation of claim 76. Note that claim 76 is withdrawn from further consideration. Insertion of the recitation of claim 76 into claim 92 would be favorably considered. In order to expedite prosecution, claim 92 will be examined inserting the recitation of claim 76 into claim 92, as has apparently been intended.

Claim 76, which is examined as part of claim 92 (and dependent claims) recites the limitation "a therapeutical composition containing purified fraction(s) of at least two compounds." This recitation is indefinite because “containing” is open language, which

permits the inclusion of elements other than purified fraction(s) in the composition. The specification defines "purified fraction" as a purified or isolated oligosaccharide fraction from natural or synthetic sources. However, the recitation of "purified" to describe a fraction which can be accompanied by any number of other elements, which could be considered impurities, is contradictory. It is unclear what is meant to be excluded by the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 92-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Pickering et al. (Infection 21 (1993) No. 6, pages 355-357).

Pickering et al. teach that breastfed infants residing in areas having poor sanitation, despite the presence of fecal organisms in colostrum of the mothers, have less occurrences of diarrhea than urban infants who were not breastfed [page 355, Epidemiologic Studies of Breastfeeding]. Human milk protects against enteropathogens such as *Vibro cholerae*, *Campylobacter jijuni*, enteropathogenic and enterotoxigenic *Escherichia coli*, Shigella, *Giardia lambia*, and rotavirus [page 355, Table 1].

Human milk is a composition which contains both LnNT and Neu5Acα3Galβ4Glc, Applicants' elected species. Human milk is a therapeutic composition, as taught by

Pickering et al. Given the broadest reasonable interpretation of the claims, as discussed in the previous rejection, the free LnNT and Neu5Acα3Galβ4Glc in human milk can be considered purified fractions within the milk composition. Infants living in areas of poor sanitation and ingesting milk contaminated with fecal organisms are considered subjects in need of treatment for bacterial infection. Thus, the claims are anticipated by Pickering et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
January 9, 2008

Shaojia Anna Jiang

4/8/08

Supervisory Patent Examiner
Art Unit 1623